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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,201	01/18/2002	Linus G. Fonkwe	4700-083 (04700.0467.4)	7237
30166	7590	12/17/2003	EXAMINER	
WOMBLE CARLYLE SANDRIDGE & RICE PLLC 300 N. GREENE STREET SUITE 1900 GREENSBORO, NC 27401			KRISHNAN, GANAPATHY	
		ART UNIT	PAPER NUMBER	
		1623	DATE MAILED: 12/17/2003	
			10	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/051,201	FONKWE ET AL.
	Examiner Ganapathy Krishnan	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3,5-24 and 26-99 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 62-93 is/are allowed.  
 6) Claim(s) 1-3,5-9,11,12,15,24-31,33,35-37,46-61 and 94-99 is/are rejected.  
 7) Claim(s) 10,13,14,16-23,32,34 and 38-45 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.                    6) Other: \_\_\_\_\_

## **DETAILED ACTION**

The Amendment B filed September 24, 2003 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 17 and 39 have been amended.
2. Claims 4 and 25 have been cancelled.
3. Remarks drawn to rejections under 35 U.S.C. 112, second paragraph rejections.

Claims 1-3, 5-24 and 26-99 are pending.

### ***Claim Objections***

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 is a duplicate of claim 5.

### ***Claim Rejections - 35 USC § 112***

The rejections of claims 17, 22, 39 and 44 have been overcome by amendment.

### ***Joint Inventors***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

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made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-9, 11, 12, 15, 24-31, 33, 35-37, 46-61 and 94-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner (WO 01/03677) in combination with Gilleland et al (WO 01/91721), Michaud et al (US 6143324) and Gilleland et al (US 6607748).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-9, 11, 12, 15, 24-31, 33, 35-37, 46-61 and 94-99 are drawn to film forming compositions comprising specific percentages/percent ranges of iota

carrageenan, kappa carrageenan, bulking agent, water and plasticizer, wherein the plasticizer is sorbitol and the bulking agent is modified starch.

Tanner et al drawn to film forming compositions, teach compositions comprising kappa/iota carrageenans, water, modified starch, and glycerin (plasticizer). Kappa carrageenan is present in the range 1 to 5.56%; iota carrageenan is present in the range 5 to 9%; water in the range 46.5 to 80%, starch (pure cote B) is 27.3% and glycerol is present in 15 and 8.3%.

Gilleland et al drawn to film forming compositions teach formulations having starch (used as a thickener), kappa carrageenan, sorbitol (plasticizer) and water (example 8, page 11) and another composition wherein the ratio of kappa and iota carrageenan is 50:50 (example 10,page 13). This combination produces a film which is stronger. Gilleland also states that a mixture of iota and kappa carrageenan should make the films easier to handle and easier seal and that blending kappa with iota carrageenan allows for higher solids while maintaining manageable viscosity. The compositions of the invention are formed by combining the dry solids, slurring in water and then heating the mixture and forming ribbons (films) and then forming coating or a capsule shell (see page 6, lines 9-25)

However, Tanner and Gilleland do not mention that starch used in their compositions is for bulking purposes.

Michaud et al et al drawn to use of starch in capsules, discloses that fillers can also act as bulking agents and in many cases this may be done using a binder and that starch is used for this purpose (col. 2, lines 8-33).

Lenaerts et al teach that starch has many uses and can act as a diluent, filler, carrier, binder, disintegrant, coating and thickener (col. 1, lines 55-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a film forming composition using a mixture of iota and kappa carrageenan and starch as a bulking agent since the ingredients and their functions are seen to be disclosed in the prior art.

One or ordinary skill in the art would be motivated to do so since Gilleland's teaching shows that a mixture comprising 1:1 kappa and iota carrageenan, starch, sorbitol and water gives a film which is strong and easy to handle and seal and also has a manageable viscosity. Hence optimizing the ratio of the ingredients would give a composition which would be ideal for use in making capsule shells.

### Conclusion

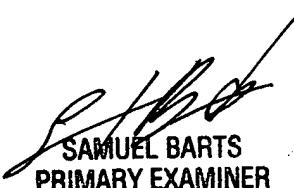
1. Claims 1-3, 5-9, 11, 12, 15, 24-31, 33, 35-37, 46-61 and 94-99 are rejected.
2. Claims 10, 13, 14, 16-23, 32, 34 and 38-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
3. Claims 62-93 which are drawn to a method of preparing the compositions is allowable since the prior art of record does not teach or render obvious the specific order in which the ingredients are mixed and heated to form the composition.

Any inquiry concerning communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached between 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax and phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



SAMUEL BARTS  
PRIMARY EXAMINER  
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